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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the one *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

ActiveInvasive EEG Device and Technique

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ENCLOSED APPLICATION PARTS *(check all that apply)*

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☐ Drawing(s) *Number of Sheets* ______
☐ Application Date Sheet. See 37 CFR 1.76
☐ CD(s), Number ______
☑ Other (specify) Attachments A thru D

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees.
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Respectfully submitted,

SIGNATURE ______

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Date 17 December 2003

REGISTRATION NO. 33,956
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Docket Number: CUtech-105P

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PROVISIONAL APPLICATION COVER SHEET
Additional Page

Docket Number	CUtech-105P

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Number 2 of 2

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Inventors: David VanSickle, M.D., Ph.D. and Ken Winston, M.D.

ACTIVEINVASIVE EEG DEVICE and TECHNIQUE

BACKGROUND OF THE INVENTION

In general, the present invention relates to electrodes used in taking invasive EEG measurement(s). EEG electrodes are often lumped into two types, surface and depth EEG electrode devices. Epilepsy is a neurological disorder characterized by the occurrence of seizures, specifically episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or the perturbation of the autonomic nervous system. Because epilepsy is characterized by seizures, its sufferers are often limited in the kinds of activities in which they may participate. Epilepsy can prevent an individual from driving, performing many tasks, and so on. Some epilepsy sufferers have serious seizures so frequently they may become incapacitated. Once diagnosed, current treatment modalities for neurological disorders, particularly epilepsy, typically involve drug therapy and surgery. Monitoring of progress is a requisite. While neurology specialists often turn first to treating epilepsy with drug therapy (since it is less surgically-invasive), drugs used are not without serious side effects and high costs. Further, for many drugs, it is important to maintain a precise therapeutic serum level to avoid breakthrough seizures (if the dosage is too low) while minimizing toxic effects (dosage gets too high). Thus, a great deal of the patient discipline is required in monitoring and treating epilepsy, especially where a patient's drug regimen causes unpleasant side effects that patient, not surprisingly, may wish to avoid. Implantable electrical stimulation of cranial nerves (especially cranial nerve XII) is also used for the treatment of epilepsy and direct stimulation of neural tissue in the vicinity of a seizure focus is an emerging therapy for seizure control.

Research on the detection has focused on receipt and analysis of waveforms referred to in scientific literature as electroencephalogram (EEG) and electrocorticogram (ECoG) waveforms. In general, EEG signals represent aggregate neuronal activity potentials detectable via electrodes applied to a patient's scalp, and EcoG(s) use internal electrodes near the surface of the brain. Thus, ECoG signals, deep-brain counterparts to EEG signals, are detectable via electrodes implanted under the dura mater (fibrous membrane forming the outermost covering of the brain and spinal cord), and usually within the patient's brain. Unless otherwise specified, "EEG" is used throughout to refer to both EEG and ECoG signals. See, also, **ATTACHMENT A**.

More-particularly, the invention is directed to a unique multifunctional *ActiveInvasive EEG* device/system and technique comprising one or more surface and/or implantable electrodes — whether depth electrodes, cortical electrodes (subdural), or epidural electrodes. As further explained by applicants in the manuscript labeled **ATTACHMENT A** (fully incorporated herein by reference) and as further supported herein, for simplicity and illustrative purposes according to the invention, focus is on surface-recording electrodes. While the focus of this technical discussion is on epileptic disorders, the device/system and technique of the invention is useful for any of a wide variety of neurological disorders experienced by human and non-human/veterinary patients.

Neurosurgeons and neurologists may use the instant invention, *ActiveInvasive EEG*, in treating patients with intractable seizures to complement and provide an optimal medical management. For example, while a patient who suffers from seizures might be treated based on MRI or other imaging evidence alone, a significant fraction will likely require either subdural or depth electrode monitoring for preoperative planning.

A conventional surface strip electrode is diagrammed in **Figure 1→** (see, also, **ATTACHMENT A**): This electrode device has a single row of six electrical contact-points embedded in a silastic matrix, each electrode point has an individual wire electrically hardwire-connecting it to an individual contact on a lead/cable. The six electrode points are conductive for contacting the tissue of the patient (where this contact occurs, depends upon the type of lead: *e.g.*, surface, subdural, epidural, *etc.*). The leads penetrate out of the skin and are connected to cabling interconnected to a recording device away from the patient (for example, see **ATTACHMENT A**, pg 13, ***Fig. 11***).

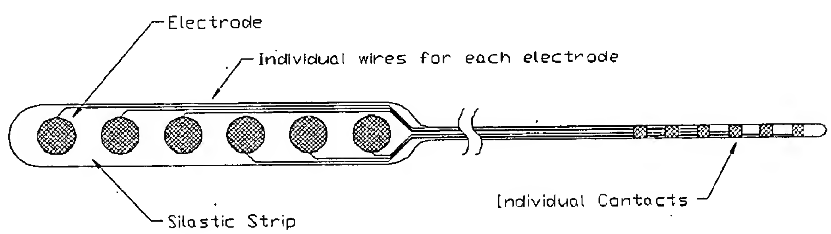

Figure 1: Simple Strip electrode device (1x6) of the type currently used. This is an example of a conventional, typical 1x6 strip electrode. Six contacts are required one for each electrode. For longer strips with more electrodes, additional contacts are required.

Invasive electroencephalogram (EEG) is a commonly used technique for surgical planning. However, current techniques for invasive EEG monitoring are cumbersome and require expensive in-hospital stays (see **ATTACHMENTS B & C**). The invention described herein is a much improved invasive EEG monitoring system (*ActiveInvasive EEG*) allowing increased convenience as well as offering a wider range of applications for invasively monitoring brain activity and treating neurological disorders (such as epilepsy), for the neurosurgeon, neurologist, associated highly trained medical technicians, and patients.

To determine if a particular individual with uncontrolled epilepsy is a surgical candidate, two fundamental areas of cerebral cortex must be distinguished, the seizure focus (or foci) and any adjacent eloquent cortex. The seizure focus is that area of cortex where seizures originate(s) and is often abnormal. Surgical resections of a patient's brain are planned and carried out by a surgeon so as to **not** lead to worsening of neurologic function. Eloquent cortex areas are those areas of brain tissue that control 'critical functions' whereby surgical resection of the area would leave a patient impaired. These areas include, but are not limited to, Broca's and Werneke's area that control speech and the motor and sensory strips located in the pre-central and post-central gyri, respectively. While these areas are known anatomically, there is a significant amount of variability between individuals and these functional areas may have been remapped to other anatomical areas due to years of seizure activity. Therefore it is extremely important to have diagnosis tools that aid in accurately identifying those sections of the brain that ought to be removed.

Multiple techniques have evolved for the localization of the seizure focus and associated eloquent cortex including imaging with PET and MRI scanners and the use of both invasive and scalp EEG recordings (for further reference, refer to **ATTACHMENT D**). While imaging techniques have the advantage of being non-invasive, not all seizure foci can be determined even with the best available technology. And while useful under certain circumstance, scalp EEG data is not as effective or consistent at lateralizing even the most common surgically treated epilepsy of the temporal lobe. In cases where the seizure focus cannot be determined through imaging, most authorities now recommend invasive EEG monitoring usually taking place in an inpatient video EEG monitoring unit. For seizures related to errors in brain development, invasive EEG is almost always required due to the unpredictability of the seizure focus and eloquent cortex.

Thus, the invention described herein is an improved system for invasive EEG recording that is more convenient for a human or veterinary patient and the neurosurgeon and neurologist, providing more accurate data delivered in a cost effective manner. In connection with surgical/ preoperative planning done by neurosurgeons and neurologists, the implantable *ActiveInvasive EEG* device with its design focused at collecting and converting nearer to the site of collection, and terminating electrical seizure activity before clinical symptoms present, provides the ability for long-term recording and/or treatment. The implantable *ActiveInvasive EEG* device, thus, gives neurosurgeons and neurologists another powerful tool for use in surgical planning, as well as in designing strategies for outpatient monitoring that employs this new invasive EEG device.

BRIEF DESCRIPTION OF DRAWINGS and ATTACHMENTS

For purposes of illustrating the innovative nature plus the flexibility of design and versatility of the electrode devices and associated technique of the invention, the following identified materials, including various pictorial representations, have been included. Throughout, the figures have been labeled consistently with those within ATTACHMENT A. One can readily appreciate the advantages and the many features that distinguish the instant invention from conventional electrodes and methods. The technical manuscript authored by the applicants hereof and other references listed, have been included to communicate the features of applicants' innovative device/system and technique by way of example, only, and are *in no way* intended to unduly limit the disclosure hereof. Each identified enclosure is labeled an ATTACHMENT and is hereby fully incorporated herein by reference to the extent consistent herewith; accordingly each ATTACHMENT is described below:

[A] David VanSickle, M.D., Ph.D. and Ken Winston, M.D., a confidential internal manuscript 13 pages in length, and which remains confidential, included herewith for its discussion of features of the invention and background information; incorporated herein in further support of the novel features of the electrode device and technique.

[B] *Information about the Epilepsy Monitoring Unit at the Cincinnati Epilepsy Center*, retrieved and printed on 05-Dec-03 from **www.med.uc.edu/neurology/emu.htm**; 4 pages in length, included herewith for its background technical reference information.

[C] **Neuroscience Center: Adult Epilepsy DIADNOSIS AND TESTING, Video EEG Monitoring (Invasive)**, retrieved & printed on 05-Dec-03 from **www.clevelandclinic.org/** 3 pages in length, included herewith for its background technical reference information concerning current invasive EEG recording procedures.

[D] **Neuroscience Center: Adult Epilepsy DIADNOSIS AND TESTING, Neuro-imaging,** retrieved & printed on 05-Dec-03 from **www.clevelandclinic.org/**; 4 pages in length, included herewith for its background technical reference information concerning current imaging techniques employed in neurology.

Figures 2 – 6 are included for purposes of supporting the representative example(s) discussed throughout; each of these figures depict various unique structures/subassemblies built according to the invention.

Figure 7 is a schematic diagram representing features of an electrode device, system and technique/method of taking invasive EEG measurements according to the invention; illustrated in **Figure 7** are not only core features, but also further distinguishing features employing one or more of the structure(s) depicted in **Figures 2 – 6** by way of example, and as discussed throughout.

BACKGROUND TECHNOLOGY: *Microelectronics and Chips/Chip-style Devices*

Microelectronics is that area of electronics technology associated with the fabrication of electronic systems or subsystems using extremely small (microcircuit-level) components. Since semiconductor fabrication and processing is driven by the computer-electronics industry, the demand for greater capability and faster data collection and processing of smaller-sized computerized units has resulted in a demand for smaller-and-smaller integrated circuit (IC) microcircuits. "Chip-style", "chip", and/or IC if and as used throughout in connection with the novel devices of the invention, includes not only the traditional use of 'chip' or 'microchip' (including any one or set of micro-miniaturized, electronic circuits, or microdevices that have been designed for use as electrical components, processors, computer memory, as well as special purpose uses in connection with consumer goods and industrial products), but also larger sized similarly-styled structures on the order of up to several cm^2. The terms chip, integrated circuit (IC), and microchip are often—as here—used interchangeably within the electronics industry.

By way of reference: microchips can hold a few to tens-of-thousands of tiny transistors—the smaller sized chips can be readily manufactured to be no more than 1/16" square by 1/30" thick, whereas larger-sized microchips of more than ½-inch square, can hold millions of transistors. It is generally the top one-thousandth of an inch of a chip's surface that holds the microcircuits, the substrate below provides mechanical strength and stability. Precision processing remains ever-more important in chip fabrication. Microcircuit wafer fabrication generally starts with a substrate to which layers, films, and coatings (such as photoresist) can be added or created (e.g., when fabricating a MOS monolithic IC, a silicon oxide layer is created on top of the silicon wafer), and from which these added or created materials can be subtractively etched (for example, as in dry etching).

DESCRIPTION DETAILING FEATURES OF THE INVENTION

As can be better appreciated by viewing the features and associated structure(s) as also outlined by applicants in **ATTACHMENT A**, further summary of the core features of the device and associated system and technique of the invention, follows. The novel multifunctional compact electrode device, system and technique is employed for the collection of information in the form of EEG waveforms from the brain of any animal (including humans as well as domesticated farm and ranch animals, pets, *etc.*, and those in the wild) in connection with the detection, monitoring, and treatment of neurological disorders, particularly epilepsy [which is often is progressive and can lead to deterioration of other brain functions as well as physical impairment(s)].

The invention includes an improved system for invasive EEG recording. In addition to reducing costs by providing a means by which monitoring for seizures may be accomplished as an outpatient or in an inpatient setting, the novel electrode devices of the invention may be left in place for extended periods of time. This also creates the option of allowing a greater number of patients to be monitored and undergo treatment. For example, a patient may have seizures that are uncontrolled by medications, but simply not frequent enough to be reliably measured during a limited one to two week in-hospital stay. One example is a patient with multiple seizure foci that can be controlled with minimal medical therapy, but one or more foci which is/are uncontrolled. This patient would not be offered surgery due to the multifocal nature of his disease. However, by leaving one or more electrode devices implanted, or otherwise placed for collecting EEG data, for an extended period(s) of time, the medications can be systematically adjusted revealing just which areas of the cortex would be amenable to surgery and which should be left intact and treated medically. Another, the ability to implant and leave an electrode(s) in longer, whether in an inpatient or outpatient setting, permits the use of focused radiosurgery for seizure foci ablation instead of the use of open surgical techniques, as is currently done. The electrodes would be implanted and the seizure focus/foci identified after appropriate systematic adjustment of the patients medications. Then, a specific focus or multiple foci would be treated using radiosurgery. The electrodes would remain in place to monitor that the seizures where indeed under control. Multiple radiosurgery sessions would be possible allowing for conservative initial treatment. After the seizures have been controlled as documented by the implanted electrodes, the electrodes would be able to be removed. A last example uses the *ActiveInvasive EEG* technology as the detection portion in a seizure termination device. Such devices may use electrical stimulation, cold, or drug therapy as a treatment modality.

The unique *ActiveInvasive EEG* comprises a combination of mechanical and functional enhancements for use in connection with invasive EEG. The enhancements are summarized in the following list—and detailed hereafter in sections labeled **C.3** - **C.7** (as in **ATTACHMENT A**):

C.3 The incorporation within the device of an integrated circuit (IC) for analog-to-digital conversion, signal integration, electrical stimulation, data storage, data transmission, *etc*.

C.4 The incorporation within the device of at least one signal bus where all of the signals are transmitted on a single wire using a transmission protocol such as the stochastic based Ethernet protocol.

C.5 The incorporation within the device of a quick connect assembly for external leads.

C.6 The incorporation within the device of power and ground planes to improve signal fidelity.

C.7 The incorporation within the device of an implanted recording/storage device for EEG information and the wireless transmission of EEG data to a remote receiving-unit.

C.3 Integrated Circuit (IC)

One key feature of the *ActiveInvasive EEG* is the incorporation of a novel integrated circuit (IC) that performs the conversion of the analog signal into a digital one (**Figure 2**) as well as providing other functionalities. This IC contains circuitry for suitable combinations of the following tasks:

1) Analog signal conditioning
2) Analog filtering
3) Analog-to-digital conversion
4) Digital filtering
5) Digital signal analysis
6) Digital data computation and transmission (*e.g.*, wireless transmission)
7) Temporary storage/memory of data

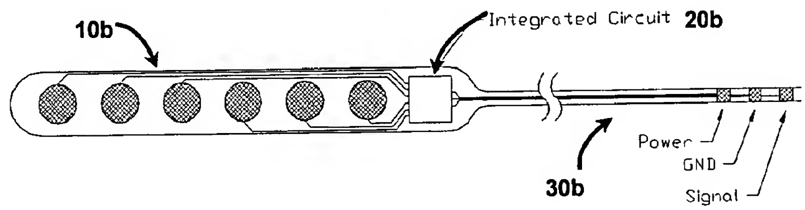

Figure 2: NEW ActiveInvasive EEG Strip electrode (1x6). For this six-position/point strip electrode, the number of contacts along the lead has been reduced to three. Also, by converting the analog signals into digital signals much closer to the source of collection, signal-to-noise ratio is improved. Additional strips with 6 or more electrode points can be interconnected while only requiring three output contacts (Power, GND, signal) for operation of the system. Thus, in the event the total number of electrode contact-points is increased within the device (*e.g.*, for technical and convenience reasons) only three output contacts will be required—as one can see, this provides a significant advantage over conventional EEG electrode technology.

Analog signal condition consists of signal amplification and appropriate scaling for later conversion to a digital signal. Analog filtering is necessary for analog-to-digital conversion to prevent aliasing where a higher frequency signal is interpreted as a lower frequency signal due to limitations based on the rate at which samples are recorded. The Nyquist criteria states that signals must sampled at twice the rate of the highest frequency in order that they be faithfully represented as a digital sequence. Since all real signals contain an infinite spectrum, the higher frequencies should be limited with analog low-pass prior to sampling. In practice, signals are acquired at a multiple of the Nyquist specified rate due to the limitations of analog filtering.

Analog-to-digital conversion closer to the source of analog signal collection markedly improves signal-to-noise ratio by decreasing overall length of wire traveled by the analog signal. Thus, the *ActiveInvasive EEG* device has significantly greater 'immunity' to noise from external sources of radiation such as sixty-cycle power transmission, radio broadcasts, and so on, that can affect readings. Digital filtering and signal analysis provides greater flexibility than analog filtering. Digital filtering also reduces cost and complexity of the circuitry; this is due in part because many of the filtering functions that can be handily performed with digital filtering, would require costly precision analog components.

Note that, according to the invention, data/information collected from the animal tissue at the various electrode contact-points may be transmitted toward a central processing area away from the patient on a single wire/cable. With the use of an appropriate protocol for data transmission, the signals for one or more of the implanted electrode strips can be transmitted over a main cable to central processing. Once again, only three output contacts are necessary regardless of total number of electrode points implanted to collect data. While, it may be desirable to increase the number of contacts for technical improvement and convenience, one benefit of the core invention is an ability to reduce total (sets) of output contacts that carry data/info collected, away from patient to a central processing area. **Figure 3** shows an example of a 6x6 grid, which as one can see, with the use of one or multiple IC's and combining outputs, requires only three contacts and one lead. Without the IC(s), a 6x6 grid array such as is shown in **Figure 3** would likely use up to six external leads with six output contacts in each.

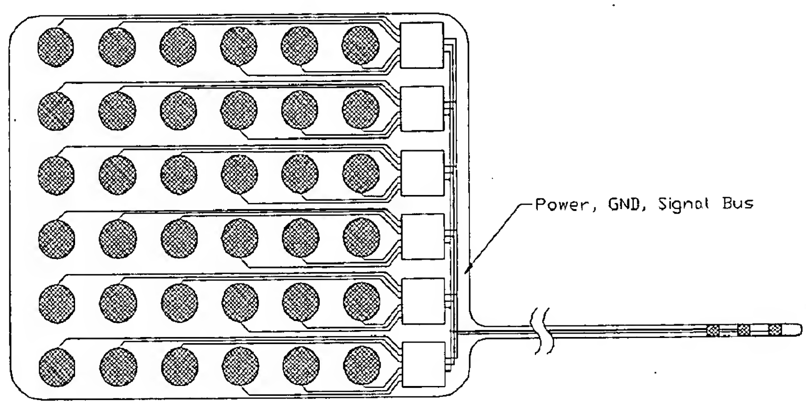

Figure 3: EXAMPLE of NEW *ActiveInvasive EEG* Grid electrode (as 6x6 grid/array). As one can see, the use of an integrated circuit (IC) unit interconnected with each strip of the overall grid limits the number of output leads to one cable and the number of output contacts thereon, to three. Note, that the power, ground (GND), and signal connections from each of the six IC's are bussed together. The number of IC's shown in this diagram is six, however, based on IC fabrication technology considerations, fewer IC's may be needed in the event each of the IC used is adapted to comprise a greater number of analog inputs.

As one can appreciate, the **Figure 3** embodiment represents only one of many suitable grid configurations of electrode points and associated IC functional units, contemplated according to the invention. For example, the electrode device may accommodate additional, or fewer IC's depending upon the number of analog inputs permitted each individual IC. The electrode contact-points are configured, for example as shown in **Figure 3** into an array/grid of rows, and incorporated into and atop a support member having a periphery of suitable shape(s) (for example, as shown in **Figure 3** the support member is rectangular in shape, while each support member in **Figures 2 & 4** are shaped as an elongated strip). The support member, as described further, is preferably multi-layered. An embodiment of the invention is the use of multiple strips or grids ganged together either with or without connectors, either semi-permanently, or permanently to be used together for adequate and/or desirable detection of seizure or other tissue electrical activity. Electrically, these multiple grids or strips are ideally connected with the power, ground and signal in parallel so that the total number of external leads is one and the total number of contacts is ideally three.

Depending on total number of electrode points interconnected with the IC, how the IC is fabricated (materials, # layers, *etc.*), total number of electrode strips, where the IC unit is located within the human or animal tissue, and so on, there may be too much thermal energy generated within and around one or more of the IC('s) during operation/use for the human or animal tissue to tolerate. Thus, an alternative location of the IC unit is contemplated remote from the electrode contacts, as shown in **Figure 4**: the IC can be placed in the subdural space. The example depicted in **Figure 4** has an IC built into the external lead/cable allowing it to be placed above the bone flap, but below the scalp where the patient's body temperature is lower.

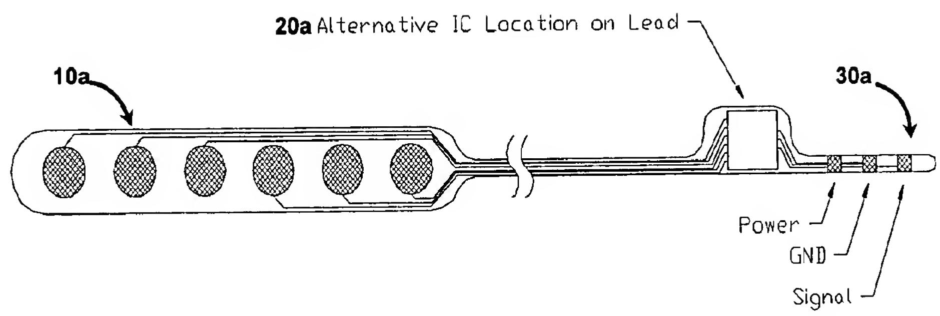

Figure 4: ActiveInvasive EEG Strip electrode (1x6) with Alternate IC Position. **The IC may be placed in a number of positions on the strip electrode. The placement of the IC on the lead may be advantageous in case of excess heat generation. In this location, the IC can be placed under the scalp away from the cortical surface.**

Preferably, and according to the invention, the IC also has additional functional capability(ies) to stimulate the brain. This allows for mapping of the eloquent areas of cortex and will provide a source of electrical stimulation in the treatment of seizures.

C.4 Signal Bus

A "bus" in an electrical circuitry is defined, generally, as: One or more conductors (conductive leads/wiring) or optical fibers (where information is transmitted via optical signals) that serves as a common connection for a group of related electronic devices/components. The use of a protocol to transmit data digitally over a single wire/cabling (using a suitable ground) is another key feature of the *Active-Invasive EEG* device of the invention. Signal transmission protocols that allow for single wire transmission (allowing for a ground return path) of digital data, already exist. One example is the stochastic Ethernet protocol. The signal output contacts of each lead can be electrically connected together as can the power and ground output contacts of each lead. With this ability, a system of 128 electrodes as part of both grids and strips implanted in a single patient would require only one external lead with three output contacts versus the minimum of 8 (assuming 16 contacts per lead) leads required with current, conventional invasive EEG systems. By reducing the number of leads, the flexibility of use/versatility of the electrode devices is greatly increased.

C.5 Unique Quick Connect Mechanism

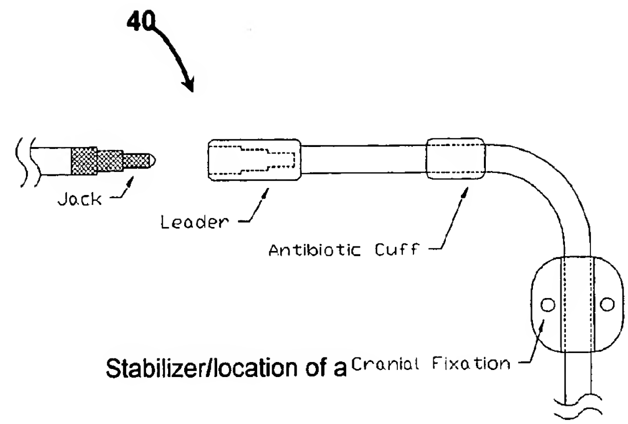

Figure 5: Quick Connect. Here, an embodiment of a quick-connect mechanism is shown having a three-conductor jack insertable into a mating receptacle/receiving end. The receptacle is attached to a lead that, upon being implanted, is tunneled out through the scalp of a patient.

Conventional EEG electrode designs have leads connected to an external recording system that do not permit the patient undergoing in-hospital treatment to move very far during the monitoring period. Instead, and preferable, is for the patient to be able to move around without danger of pulling the electrode grids or strips from their surgically implanted locations. A quick-connect mechanism having the proximal portion anchored to the skull with suitable fastener(s) - for example, as shown and labeled 'stabilizer' in **Figure 5** (preferably attached at a suitable cranial fixation location) - is contemplated here. Suitable fasteners include screws similar in design to existing plating systems currently used for fixation of bone flaps created during craniotomy surgery. The embodiment shown in **Figure 5** has a three-conductor jack that is inserted into a receptacle/receiving end (labeled 'leader'). The receiving receptacle is attached to the portion of the lead that, in operation as implanted, has been tunneled out through the scalp.

An antibiotic cuff is incorporated into the device as shown in **Figure 5**, to prevent infection from traversing the tunnel and [in]to the patient. Therefore, if the patient through normal movement or as part of a seizure moves in a manner to cause strain on the external recording system, the connector mechanism will pull apart rather than having the strips of electrode points be dislodged. The quick-connect is designed such that the force required to pull-apart the jack and receiving end be sufficient to hold the mechanism together during monitoring and/or treatment, yet light enough to permit the mechanism to pull apart before the grids or strips of electrode contacts experience force enough to cause them to be displaced. During monitoring, in the event the connect mechanism is - whether due to seizure or other disturbance to the patient (*e.g.*, the patient needs to use a rest room) - disconnected, the electrode device(s) implanted in the patient may simply be reconnected to the external recording unit/system in a 'snap'.

C.6 Power and Ground Planes

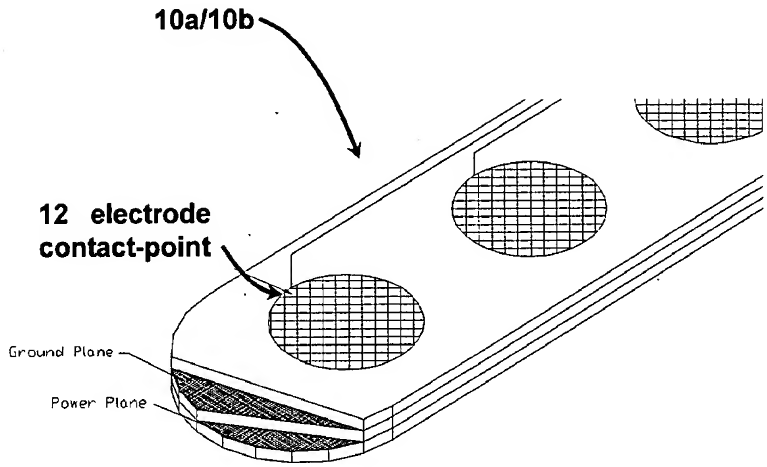

Figure 6: Power Planes and Ground Planes. This cutaway illustrates an embodiment of a strip electrode device that has both power and ground planes incorporated within a support member for the electrode contact-points comprising, for example, a silastic membrane/material.

Printed circuit boards used in computerized devices are built with the capability to 'shun' interference due to external electromagnetic (EM) radiation from power lines, RF (radio freq) emissions, *etc.*, in part due to power and ground planes that are incorporated into the layers. Unfortunately, EM signals/radiation can interfere with both surface and invasive EEG monitoring.

Power and ground planes provide an EM shielding for the electrode contact-points. A Gaussian surface might be described generally, as follows: If a charged particle is located inside of a perfectly conducting sphere then the charge cannot be detected outside the sphere due to the cancellation from the induced charge in the sphere. An infinite plane is simply a sphere with an infinite radius. Therefore, a charge from one side of an infinite plane cannot be detected on the other side of such a plane. While an infinite plane is impractical to manufacture, it may be sufficiently estimated in fabrication: Many of the benefits of a perfectly conducting infinite plane can be realized by use of real conducting plane overlying an electrical circuit. Incorporated into the electrode device of the invention, is the use of a multi-layered member. As depicted in **Figure 6**, two planes made from electrically conductive material such as, but not limited to, silver built into the silastic membrane member supporting the electrode contact-points of the strip or grid electrodes. This arrangement is depicted in the cutaway **Figure 6.** The large conducting planes will shield the electrode contact-points on the support member. As mentioned above, the support member is thus, preferably multi-layered and of suitable shape depending upon the electrode contact-point configuration selected. Furthermore, by using two planes very close together with one connected to the regulated power of the IC and one connected to ground, any charge induced on one plane can very nearly be cancelled by the other plane. Thus, at least one conductive plane is incorporated into the support member (for example, comprising the silastic membrane or other flexible, non-conducting, biocompatible-type material), and preferably two planes are incorporated into the support member.

C.7 Implantable Data Collecting/Recording Device with Wireless Transmission

For extended long-term use, it is preferable to have no external, hardwire connection to the *ActiveInvasive EEG* electrode devices implanted into a patient. An embodiment that is comprised of implantable electrode devices having no external lead hardwired to a recording/central processing unit, is contemplated (*e.g.*, **Figure 7**, 100b). In the event that there is insufficient space in the subgalial compartment to house such a device, locations such as in axilla may be used, as has been done in the past successfully for devices such as the vagal nerve stimulator and the deep brain stimulator. Furthermore, tunneling techniques have already been devised and are in use for the routing of the leads for EEG devices. These tunneling techniques are, in turn, based on techniques for the placement of shunts for hydrocephalus. Placing an implantable recorder-processor unit in the axilla or other convenient corporeal compartment, an output lead comprising the three conductors (dedicated for power, ground, and signal, such as is shown in **Figures 2- 4**) may be routed from the subgalial space under the subcutaneous tissue to an implantable, or externally worn (*e.g.*, a hand-held sized unit), recorder-processor unit. Note, once again, that a minimum of three conductors (power, ground, signal) is preferred, however, more or fewer than three conductors may be used according to the invention.

In this embodiment, the recorder-processor unit is adapted for receiving and storing the data collected and digitally converted, and for wireless transmission 75 to a host/central processing unit. While it may be desirable to implant a small unit comprising a data storage device, power source (battery) and wireless transmission capability at a site remote from the electrode devices, using current microcircuit technology, data storage, power source(s), and wireless EM data transmission capability(ies) may be located on the electrode itself and built into one of more IC (*e.g.*, 20a/20b) of the device, further reducing the total number of components. Note that the recorder-processor unit may alternatively be worn by a patient 60.

Summary

Neurosurgeons and neurologists may use the *ActiveInvasive EEG* devices in treating patients with intractable seizures to complement and provide an optimal medical management. Between 0.5 and 1.0% of the population have seizures with approximately 20% of these having poor control with medications. Many of these individuals might be treated based on MRI or other imaging evidence alone; however, a significant fraction likely require either subdural, epidural or depth electrode monitoring for preoperative planning. The *ActiveInvasive EEG* devices each can comprise one or more chips with a minimal number of supporting components, including fabrication by embedding the IC into a silastic membrane supporting electrode contact-points configured in an array/grid or along a strip. Electrode contact-points, leads, and output contacts can be fabricated from existing materials. While techniques for wireless transmission of data/information exist, as applied here to the *ActiveInvasive EEG* devices, is unique.

Several embodiments of the unique features are contemplated - schematically represented in **Figure 7** with features identified thereon, for handy reference - each embodiment may be termed a "*stage*" for reference: "*first stage*" device incorporates the unique IC (*e.g.*, 10a/10b - having one or more of the capabilities discussed) and associated digital signal bus to reduce the number of output leads to, for example, three. Furthermore, the electrode devices 100a/100b - since they are adapted for fabrication as disposable devices comprising electrode contact-points in selected configuration atop a support member - can aid in reducing overall cost of capital equipment for invasive EEG recording. This stage will also incorporate the unique quick-connect 40, multiple planes (GND, power, signal - see **Figure 6**, for example). A "*second stage*" device incorporates, alone or in addition to features of the *first stage* device and the recorder-processor unit (*e.g.*, a tiny implantable unit incorporated into the electrode device or worn by a patient 60). While transmission medium 30b is shown as a hardwire connection, it need not be: Depending upon its location - whether implanted - IC 20b may be further adapted to transmit wirelessly to unit 60, which can store and transmit 75 periodically as a downloading of a collection/compilation of processed digital data. A "*third stage*" device incorporates capabilities for employing the new *ActiveInvasive EEG* device as a research tool for collecting valuable data/information permitting a trained medical professional to predict clinical seizure activity and, using that information, terminate seizure(s) electrically.

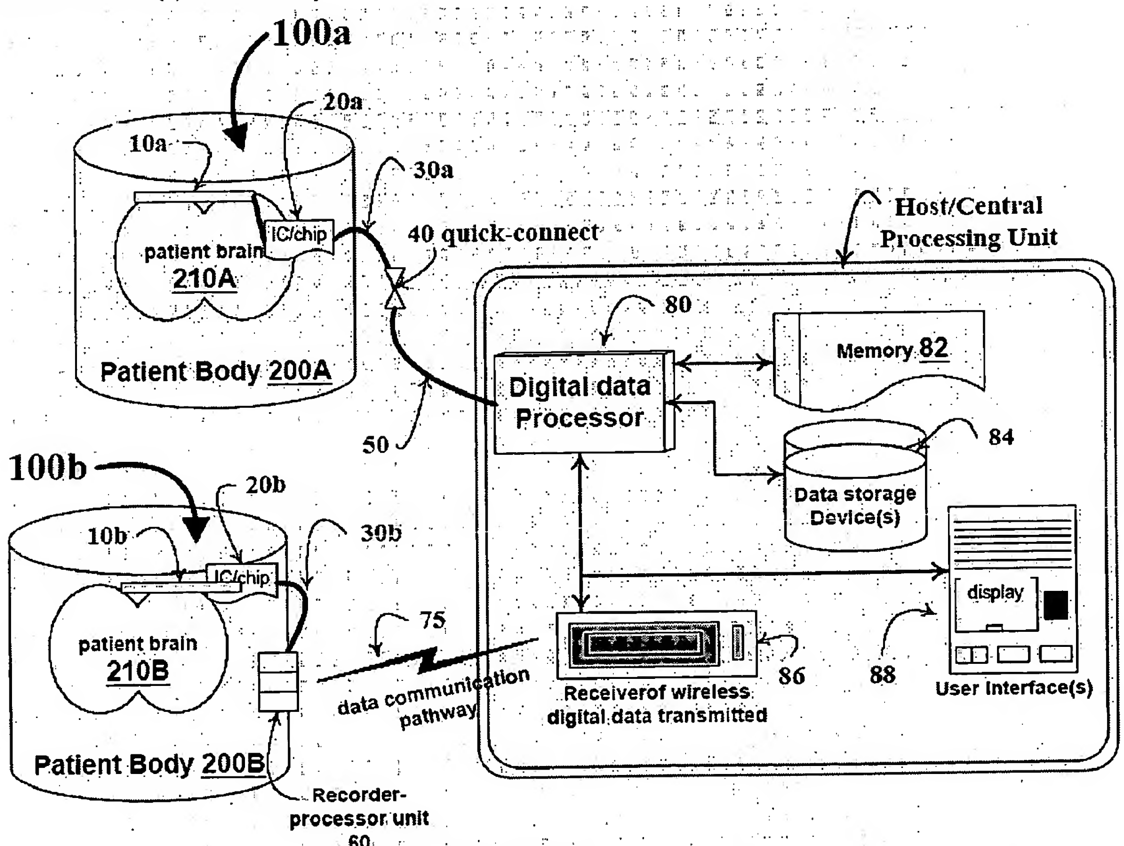

Figure 7

While certain representative embodiments and details of an example have been shown merely for the purpose of illustrating the unique electrode devices and in combination, associated system and technique of the invention, those skilled in the art will readily appreciated that various modifications may be made to representative embodiments without departing from the novel teachings or scope of this technical disclosure. Accordingly, all such modifications are intended and contemplated as included within the scope hereof. Although the commonly employed preamble phrase "comprising the steps of" may be used herein, or hereafter, in a method claim, the applicants do not intend to invoke 35 U.S.C. Section 112 §6. Furthermore, in any claim that is filed (herein for illustrative purposes as well as claims added hereafter in a utility application), any means-plus-function clauses used, or later found to be present, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but *also* equivalent structures.

For exemplary purposes only, the following is offered as an outline of the unique technology disclosed, using terminology consistent with US patent claim(ing) conventions:

1. An electrode device for taking a plurality of invasive EEG measurements, the device comprising:

(a) a plurality of electrode contact-points configured atop a support member comprising a plurality of layers;

(b) said contact-points in electrical communication with an integrated circuit comprising converter circuitry adapted for converting analog EEG signals measured from within a patient, into digital signals; and

(c) said integrated circuit in further electrical communication with a lead assembly having wiring for electrical transmission of said digital signals and for a ground reference.

2. The electrode device of claim 1 wherein:

(a) said plurality of layers of said support member comprise a power plane and a ground reference plane; and

(b) said integrated circuit further comprises circuitry for digital filtering and signal analysis of said digital signals.

3. The electrode device of claim 1:

further comprising **(a)** a quick-connect mechanism located along said lead assembly

between said integrated circuit and a host processing unit, and **(b)** an antibiotic cuff mechanism located along said lead assembly between said quick-connect mechanism and a stabilizer of said lead assembly to a location on said patient; and

(c) wherein said support member is generally flexible.

4. The electrode device of claim 1 wherein said integrated circuit further comprises circuitry for

(a) digital filtering of said digital signals;

(b) signal analysis and processing of said digital signals;

(c) memory storage of said processed digital signals; and

(d) transmission outwardly from said patient, of electromagnetic waves comprising information about said processed digital signals.

5. The electrode device of claim 1:

(a) wherein said integrated circuit further comprises circuitry for digital filtering and signal analysis of said digital signals; and

(b) further comprising a recorder-processor unit adapted to be worn by said patient, and a transmission medium disposed between said integrated circuit and said recorder-processor unit for regular transmission of information about said digital signals from said integrated circuit.

6. The electrode device of claim 5 wherein said transmission medium is selected from the group consisting of **(a)** air, wherein said regular transmission of said information is performed as wireless transmission, and **(b)** cabling, a first end of which is in electrical communication with said integrated circuit and a second end of which is connected to said recorder-processor unit.

7. A method of taking a plurality of invasive EEG measurements, the method comprising:

(a) measuring analog EEG signals from within a patient through a plurality of electrode contact-points configured atop a support member comprising a plurality of layers;

(b) converting said analog EEG signals measured, into digital signals using circuitry of an integrated circuit in communication with said patient; and

(c) electrically transmitting said digital signals from said integrated circuit through a lead assembly having a wiring for a ground reference, and further to a host processing unit.

8. The method of claim 7 further comprising, before said step of measuring analog EEG signals, joining a quick-connect mechanism located along said lead assembly between said integrated circuit and said host processing unit, for providing a hardwire electrical connection for performing said step of electrically transmitting further to said host processing unit.

9. The method of claim 7:

(a) further comprising, after said step of converting said analog EEG signals and prior to performing said step of electrically transmitting from said integrated circuit, the steps of: filtering said digital signals, processing said digital signals, and storing said processed digital signals; and

(b) wherein said step of electrically transmitting from said integrated circuit further comprises: transmitting through said lead assembly to a recorder-processor unit, and transmitting electromagnetic waves comprising information about said processed digital signals, outwardly from said recorder-processor unit.

10. A method of taking a plurality of invasive EEG measurements, the method comprising:

(a) measuring analog EEG signals from within a patient through a plurality of electrode contact-points configured atop a support member;

(b) converting said analog EEG signals measured, into digital signals using circuitry of an integrated circuit in communication with said patient;

(c) electrically transmitting outwardly from said integrated circuit, electromagnetic waves comprising information about said digital signals.

11. The method of claim 10 wherein said step of electrically transmitting from said integrated circuit further comprises:

(a) transmitting said electromagnetic waves to a remote recorder-processor unit adapted to be worn by said patient;

(b) processing said information at said recorder-processor unit; and

(c) further transmitting said processed information about said digital signals to a host processing unit.

12. The method of claim 10:

(a) further comprising, after said step of converting said analog EEG signals and

prior to performing said step of electrically transmitting from said integrated circuit, the steps of filtering and analyzing said digital signals; and

(b) wherein said step of electrically transmitting from said integrated circuit further comprises: transmitting said digital signals from said integrated circuit through a lead assembly having wiring for a ground reference and for supplying power, and transmitting through a quick-connect mechanism to a host processing unit.